

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 3580**

OFFERED BY MR. TAUZIN

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Medical Device User Fee and Modernization Act of
4 2002”.

5 (b) TABLE OF CONTENTS.—The table of contents for
6 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—FEES RELATED TO MEDICAL DEVICES

Sec. 101. Findings.
Sec. 102. Establishment of program.
Sec. 103. Annual reports.
Sec. 104. Postmarket surveillance.
Sec. 105. Consultation.
Sec. 106. Effective date.
Sec. 107. Sunset clause.

**TITLE II—AMENDMENTS REGARDING REGULATION OF MEDICAL
DEVICES**

Sec. 201. Inspections by accredited persons.
Sec. 202. Third party review of premarket notification.
Sec. 203. Designation and regulation of combination products.
Sec. 204. Report on certain devices.
Sec. 205. Electronic labeling.
Sec. 206. Electronic registration.
Sec. 207. Intended use.
Sec. 208. Modular review.
Sec. 209. Pediatric expertise regarding classification-panel review of premarket applications.
Sec. 210. Internet list of class II devices exempted from requirement of premarket notification.



- Sec. 211. Study by Institute of Medicine of postmarket surveillance regarding pediatric populations.
Sec. 212. Guidance regarding pediatric devices.
Sec. 213. Breast implants; study by Comptroller General.
Sec. 214. Breast implants; research through National Institutes of Health.

TITLE III—ADDITIONAL AMENDMENTS

- Sec. 301. Identification of manufacturer of medical devices.
Sec. 302. Single-use medical devices.

1 **TITLE I—FEES RELATED TO** 2 **MEDICAL DEVICES**

3 **SEC. 101. FINDINGS.**

4 The Congress finds that—

5 (1) prompt approval and clearance of safe and
6 effective devices is critical to the improvement of the
7 public health so that patients may enjoy the benefits
8 of devices to diagnose, treat, and prevent disease;

9 (2) the public health will be served by fur-
10 nishing additional funds for the review of devices so
11 that statutorily mandated deadlines may be met; and

12 (3) the fees authorized by the amendment made
13 by section 102 will be dedicated to meeting the goals
14 identified in the letters from the Secretary of Health
15 and Human Services to the Committee on Energy
16 and Commerce of the House of Representatives and
17 the Committee on Health, Education, Labor, and
18 Pensions of the Senate.

19 **SEC. 102. ESTABLISHMENT OF PROGRAM.**

20 (a) IN GENERAL.—Subchapter C of chapter VII of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.



1 379F et seq.) is amended by adding at the end the fol-
2 lowing part:

3 **“PART 3—FEES RELATING TO DEVICES**

4 **“SEC. 737. DEFINITIONS.**

5 “For purposes of this subchapter:

6 “(1) The term ‘premarket application’ means—

7 “(A) an application for approval of a de-
8 vice submitted under section 515(c) or section
9 351 of the Public Health Service Act; or

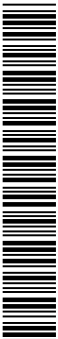
10 “(B) a product development protocol de-
11 scribed in section 515(f).

12 Such term does not include a supplement, a pre-
13 market report, or a premarket notification submis-
14 sion.

15 “(2) The term ‘premarket report’ means a re-
16 port submitted under section 510(o)(3).

17 “(3) The term ‘premarket notification submis-
18 sion’ means a report submitted under section
19 510(k).

20 “(4)(A) The term ‘supplement’, with respect to
21 a panel-track supplement, a 180-day supplement, a
22 real-time supplement, or an efficacy supplement,
23 means a request to the Secretary to approve a
24 change in a device for which—



1 “(i) an application has been approved
2 under section 515(d) or under section 351 of
3 the Public Health Service Act; or

4 “(ii) a notice of completion has become ef-
5 fective under section 515(f).

6 “(B) The term ‘panel-track supplement’ means
7 a supplement to an approved premarket application
8 under section 515 that requests a significant change
9 in design or performance of the device, or a new in-
10 dication for use of the device, and for which clinical
11 data are generally necessary to provide a reasonable
12 assurance of safety and effectiveness.

13 “(C) The term ‘180-day supplement’ means a
14 supplement to an approved premarket application
15 under section 515 that is not a panel-track supple-
16 ment and requests a significant change in compo-
17 nents, materials, design, specification, software,
18 color additives, or labeling.

19 “(D) The term ‘real-time supplement’ means a
20 supplement to an approved premarket application
21 under section 515 that requests a minor change to
22 the device, such as a minor change to the design of
23 the device, software, manufacturing, sterilization, or
24 labeling, and for which the applicant has requested
25 and the agency has granted a meeting or similar



1 forum to jointly review and determine the status of
2 the supplement.

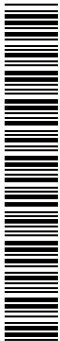
3 “(E) The term ‘efficacy supplement’ means a
4 supplement to an approved premarket application
5 under section 351 of the Public Health Service Act
6 that requires substantive clinical data.

7 “(5) The term ‘process for the review of device
8 applications’ means the following activities of the
9 Secretary with respect to the review of premarket
10 applications, premarket reports, supplements, and
11 premarket notification submissions:

12 “(A) The activities necessary for the re-
13 view of premarket applications, premarket re-
14 ports, supplements, and premarket notification
15 submissions.

16 “(B) The issuance of action letters that
17 allow the marketing of devices or which set
18 forth in detail the specific deficiencies in such
19 applications, reports, supplements, or submis-
20 sions and, where appropriate, the actions nec-
21 essary to place them in condition for approval.

22 “(C) The inspection of manufacturing es-
23 tablishments and other facilities undertaken as
24 part of the Secretary’s review of pending pre-



1 market applications, premarket reports, and
2 supplements.

3 “(D) Monitoring of research conducted in
4 connection with the review of such applications,
5 reports, supplements, and submissions.

6 “(E) Review of device applications subject
7 to section 351 of the Public Health Service Act
8 for an investigational new drug application
9 under section 505(i) or for an investigational
10 device exemption under section 520(g) and ac-
11 tivities conducted in anticipation of the submis-
12 sion of such applications under section 505(i)
13 or 520(g).

14 “(F) The development of guidance, policy
15 documents, or regulations to improve the proc-
16 ess for the review of premarket applications,
17 premarket reports, supplements, and premarket
18 notification submissions.

19 “(G) The development of voluntary test
20 methods, consensus standards, or mandatory
21 performance standards under section 514 in
22 connection with the review of such applications,
23 reports, supplements, or submissions and re-
24 lated activities.



1 “(H) The provision of technical assistance
2 to device manufacturers in connection with the
3 submission of such applications, reports, supple-
4 ments, or submissions.

5 “(I) Any activity undertaken under section
6 513 or 515(i) in connection with the initial clas-
7 sification or reclassification of a device or under
8 section 515(b) in connection with any require-
9 ment for approval of a device.

10 “(J) Evaluation of postmarket studies re-
11 quired as a condition of an approval of a pre-
12 market application under section 515 or section
13 351 of the Public Health Service Act.

14 “(K) Compiling, developing, and reviewing
15 information on relevant devices to identify safe-
16 ty and effectiveness issues for devices subject to
17 premarket applications, premarket reports, sup-
18 plements, or premarket notification submis-
19 sions.

20 “(6) The term ‘costs of resources allocated for
21 the process for the review of device applications’
22 means the expenses incurred in connection with the
23 process for the review of device applications for—

24 “(A) officers and employees of the Food
25 and Drug Administration, contractors of the



1 Food and Drug Administration, advisory com-
2 mittees, and costs related to such officers, em-
3 ployees, and committees and to contracts with
4 such contractors;

5 “(B) management of information, and the
6 acquisition, maintenance, and repair of com-
7 puter resources;

8 “(C) leasing, maintenance, renovation, and
9 repair of facilities and acquisition, maintenance,
10 and repair of fixtures, furniture, scientific
11 equipment, and other necessary materials and
12 supplies; and

13 “(D) collecting fees and accounting for re-
14 sources allocated for the review of premarket
15 applications, premarket reports, supplements,
16 and submissions.

17 “(7) The term ‘adjustment factor’ applicable to
18 a fiscal year is the Consumer Price Index for all
19 urban consumers (all items; United States city aver-
20 age) for April of the preceding fiscal year divided by
21 such Index for April 2002.

22 “(8) The term ‘affiliate’ means a business entity
23 that has a relationship with a second business entity
24 if, directly or indirectly—



1 “(A) one business entity controls, or has
2 the power to control, the other business entity;
3 or

4 “(B) a third party controls, or has power
5 to control, both of the business entities.

6 **“SEC. 738. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

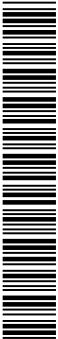
7 “(a) TYPES OF FEES.—Beginning on the date of the
8 enactment of the Medical Device User Fee and Moderniza-
9 tion Act of 2002, the Secretary shall assess and collect
10 fees in accordance with this section as follows:

11 “(1) PREMARKET APPLICATION, PREMARKET
12 REPORT, SUPPLEMENT, AND SUBMISSION FEE.—

13 “(A) IN GENERAL.—Except as provided in
14 subparagraph (B) and subsection (d), each per-
15 son who submits any of the following, on or
16 after October 1, 2002, shall be subject to a fee
17 established under subsection (c)(5) for the fis-
18 cal year involved in accordance with the fol-
19 lowing:

20 “(i) A premarket application.

21 “(ii) For a premarket report, a fee
22 equal to the fee that applies under clause
23 (i).



1 “(iii) For a panel track supplement, a
2 fee equal to the fee that applies under
3 clause (i).

4 “(iv) For a 180-day supplement, a fee
5 equal to 21.5 percent of the fee that ap-
6 plies under clause (i), subject to any ad-
7 justment under subsection (c)(3).

8 “(v) For a real-time supplement, a fee
9 equal to 7.2 percent of the fee that applies
10 under clause (i).

11 “(vi) For an efficacy supplement, a
12 fee equal to the fee that applies under
13 clause (i).

14 “(vii) For a premarket notification
15 submission, a fee equal to 1.75 percent of
16 the fee that applies under clause (i), sub-
17 ject to any adjustment under subsection
18 (c)(3).

19 “(B) EXCEPTIONS.—

20 “(i) HUMANITARIAN DEVICE EXEMP-
21 TION.—A device for which a humanitarian
22 device exemption has been granted is not
23 subject to the fees established in subpara-
24 graph (A).



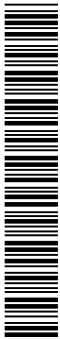
1 “(ii) FURTHER MANUFACTURING
2 USE.—No fee shall be required under sub-
3 paragraph (A) for the submission of a pre-
4 market application under section 351 of
5 the Public Health Service Act for a prod-
6 uct licensed for further manufacturing use
7 only.

8 “(iii) STATE OR FEDERAL GOVERN-
9 MENT SPONSORS.—No fee shall be re-
10 quired under subparagraph (A) for a pre-
11 market application, premarket report, sup-
12 plement, or premarket notification submis-
13 sion submitted by a State or Federal Gov-
14 ernment entity unless the device involved is
15 to be distributed commercially.

16 “(iv) PREMARKET NOTIFICATIONS BY
17 THIRD PARTIES.—No fee shall be required
18 under subparagraph (A) for a premarket
19 notification submission reviewed by an ac-
20 credited person pursuant to section 523.

21 “(v) PEDIATRIC CONDITIONS OF
22 USE.—

23 “(I) IN GENERAL.—No fee shall
24 be required under subparagraph (A)
25 for a premarket application or pre-



1 market notification submission if the
2 proposed conditions of use for the de-
3 vice involved are solely for a pediatric
4 population. No fee shall be required
5 under such subparagraph for a sup-
6 plement if the sole purpose of the sup-
7 plement is to propose conditions of
8 use for a pediatric population.

9 “(II) SUBSEQUENT PROPOSAL OF
10 ADULT CONDITIONS OF USE.—In the
11 case of a person who submits a pre-
12 market application for which, under
13 subclause (I), a fee under subpara-
14 graph (A) is not required, any supple-
15 ment to such application that pro-
16 poses conditions of use for any adult
17 population is subject to the fee that
18 applies under such subparagraph for a
19 premarket application.

20 “(C) PAYMENT.—The fee required by sub-
21 paragraph (A) shall be due upon submission of
22 the premarket application, premarket report,
23 supplement, or premarket notification submis-
24 sion except that invoices for applications sub-
25 mitted between October 1, 2002, and the date



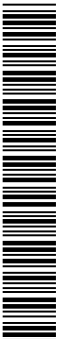
1 of the enactment of the Medical Device User
2 Fee and Modernization Act of 2002 shall be
3 payable on October 30, 2002. Applicants sub-
4 mitting portions of applications pursuant to
5 section 515(c)(3) shall pay such fees upon sub-
6 mission of the first portion of such applications.
7 The fees credited to fiscal year 2003 under this
8 section shall include all fees payable from Octo-
9 ber 1, 2002, through September 30, 2003.

10 “(D) REFUNDS.—

11 “(i) APPLICATION REFUSED FOR FIL-
12 ING.—The Secretary shall refund 75 per-
13 cent of the fee paid under subparagraph
14 (A) for any application or supplement that
15 is refused for filing.

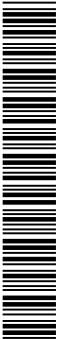
16 “(ii) APPLICATION WITHDRAWN BE-
17 FORE FILING.—The Secretary shall refund
18 75 percent of the fee paid under subpara-
19 graph (A) for any application or supple-
20 ment that is withdrawn prior to the filing
21 decision of the Secretary.

22 “(iii) APPLICATION WITHDRAWN BE-
23 FORE FIRST ACTION.—After receipt of a
24 request for a refund of the fee paid under
25 subparagraph (A) for a premarket applica-



1 tion, premarket report, or supplement that
2 is withdrawn after filing but before a first
3 action, the Secretary may return some or
4 all of the fee. The amount of refund, if
5 any, shall be based on the level of effort al-
6 ready expended on the review of such ap-
7 plication, report, or supplement. The Sec-
8 retary shall have sole discretion to refund
9 a fee or portion of the fee under this sub-
10 paragraph. A determination by the Sec-
11 retary concerning a refund under this
12 paragraph shall not be reviewable.

13 “(b) FEE REVENUE AMOUNTS.—Except as provided
14 in subsections (c), (d), (f), and (g), the fees under sub-
15 section (a) shall be established to generate the following
16 revenue amounts: \$25,125,000 in fiscal year 2003;
17 \$27,255,000 in fiscal year 2004; \$29,785,000 in fiscal
18 year 2005; \$32,615,000 in fiscal year 2006, and
19 \$35,000,000 in fiscal year 2007. If legislation is enacted
20 after the date of the enactment of this Act requiring the
21 Secretary to fund additional costs of the retirement of
22 Federal personnel, fee revenue amounts under this sub-
23 section shall be increased in each year by the amount nec-
24 essary to fully fund the portion of such additional costs



1 that are attributable to the process for the review of device
2 applications.

3 “(c) ADJUSTMENTS.—

4 “(1) INFLATION ADJUSTMENT.—The revenues
5 established in subsection (b) shall be adjusted by the
6 Secretary by notice, published in the Federal Reg-
7 ister, for a fiscal year to reflect the greater of—

8 “(A) the total percentage change that oc-
9 curred in the Consumer Price Index for all
10 urban consumers (all items; U.S. city average)
11 for the 12 month period ending June 30 pre-
12 ceding the fiscal year for which fees are being
13 established, or

14 “(B) the total percentage change for the
15 previous fiscal year in basic pay under the Gen-
16 eral Schedule in accordance with section 5332
17 of title 5, United States Code, as adjusted by
18 any locality-based comparability payment pur-
19 suant to section 5304 of such title for Federal
20 employees stationed in the District of Columbia.

21 The adjustment made each fiscal year by this sub-
22 section shall be added on a compounded basis to the
23 sum of all adjustments made each fiscal year after
24 fiscal year 2003 under this subsection.

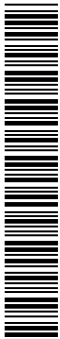


1 “(2) WORKLOAD ADJUSTMENT.—After the fee
2 revenues established in subsection (b) are adjusted
3 for a fiscal year for inflation in accordance with
4 paragraph (1), the fee revenues shall, beginning with
5 fiscal year 2004, be adjusted further each fiscal year
6 to reflect changes in the workload of the Secretary
7 for the process for the review of device applications.
8 With respect to such adjustment:

9 “(A) The adjustment shall be determined
10 by the Secretary based on a weighted average
11 of the change in the total number of premarket
12 applications, investigational new device applica-
13 tions, premarket reports, supplements, and pre-
14 market notification submissions submitted to
15 the Secretary. The Secretary shall publish in
16 the Federal Register the fee revenues and fees
17 resulting from the adjustment and the sup-
18 porting methodologies.

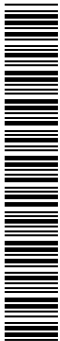
19 “(B) Under no circumstances shall the ad-
20 justment result in fee revenues for a fiscal year
21 that are less than the fee revenues for the fiscal
22 year established in subsection (b), as adjusted
23 for inflation under paragraph (1).

24 “(3) COMPENSATING ADJUSTMENT.—After the
25 fee revenues established in subsection (b) are ad-



1 justed for a fiscal year for inflation in accordance
2 with paragraph (1), and for workload in accordance
3 with paragraph (2), the fee revenues shall, beginning
4 with fiscal year 2004, be adjusted further each fiscal
5 year, if necessary, to reflect the cumulative amount
6 by which collections for previous fiscal years, begin-
7 ning with fiscal year 2003, fell below the cumulative
8 revenue amounts for such fiscal years specified in
9 subsection (b), adjusted for such fiscal years for in-
10 flation in accordance with paragraph (1), and for
11 workload in accordance with paragraph (2). Only
12 fees for 180 day supplements and premarket notifi-
13 cation submissions shall be increased to generate
14 compensating adjustment revenues.

15 “(4) FINAL YEAR ADJUSTMENT.—For fiscal
16 year 2007, the Secretary may, in addition to adjust-
17 ments under paragraphs (1) and (2), further in-
18 crease the fees and fee revenues established in sub-
19 section (b) if such adjustment is necessary to pro-
20 vide for not more than three months of operating re-
21 serves of carryover user fees for the process for the
22 review of device applications for the first three
23 months of fiscal year 2008. If such an adjustment
24 is necessary, the rationale for the amount of the in-
25 crease shall be contained in the annual notice estab-



1 lishing fee revenues and fees for fiscal year 2007. If
2 the Secretary has carryover user fee balances for
3 such process in excess of three months of such oper-
4 ating reserves, the adjustment under this paragraph
5 shall not be made.

6 “(5) ANNUAL FEE SETTING.—The Secretary
7 shall, 60 days before the start of each fiscal year
8 after September 30, 2002, establish, for the next fis-
9 cal year, and publish in the Federal Register, fees
10 under subsection (a), based on the revenue amounts
11 established under subsection (b) and the adjustment
12 provided under this subsection, except that the fees
13 established for fiscal year 2003 shall be based on a
14 premarket application fee of \$139,000.

15 “(6) LIMIT.—The total amount of fees charged,
16 as adjusted under this subsection, for a fiscal year
17 may not exceed the total costs for such fiscal year
18 for the resources allocated for the process for the re-
19 view of device applications.

20 “(d) SMALL BUSINESS FEE WAIVER AND FEE RE-
21 DUCATION.—

22 “(1) IN GENERAL.—The Secretary shall grant a
23 waiver of the fee required under subsection (a) for
24 one premarket application, or one premarket report,
25 where the Secretary finds that the applicant involved



1 is a small business submitting its first premarket
2 application to the Secretary, or its first premarket
3 report, respectively, for review. In addition, for sub-
4 sequent premarket applications, premarket reports,
5 and supplements where the Secretary finds that the
6 applicant involved is a small business, the fees speci-
7 fied in clauses (i) through (vi) of subsection
8 (a)(1)(A) may be paid at a reduced rate in accord-
9 ance with paragraph (2)(C).

10 “(2) RULES RELATING TO SMALL BUSI-
11 NESSES.—

12 “(A) DEFINITION.—

13 “(i) For purposes of this subsection,
14 the term ‘small business’ means an entity
15 that reported \$10,000,000 or less of gross
16 receipts or sales in its most recent Federal
17 income tax return for a taxable year, in-
18 cluding such returns of all of its affiliates,
19 partners, or parent firms.

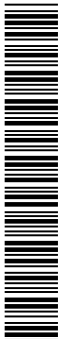
20 “(ii) The Secretary may adjust the
21 \$10,000,000 threshold established in
22 clause (i) if the Secretary has evidence
23 from actual experience that this threshold
24 results in a reduction in revenues from
25 premarket applications, premarket reports,



1 and supplements that is 13 percent or
2 more than would occur without small busi-
3 ness exemptions and lower fee rates. To
4 adjust this threshold, the Secretary shall
5 publish a notice in the Federal Register
6 setting out the rationale for the adjust-
7 ment, and the new threshold.

8 “(B) EVIDENCE OF QUALIFICATION.—An
9 applicant shall pay the higher fees established
10 by the Secretary each year unless the applicant
11 submits evidence that it qualifies for a waiver
12 of the fee or the lower fee rate. The applicant
13 shall support its claim that it meets the defini-
14 tion under subparagraph (A) by submission of
15 a copy of its most recent Federal income tax re-
16 turn for a taxable year, which shows an amount
17 of gross sales or receipts that is less than the
18 maximum established in subparagraph (A). The
19 applicant shall certify that the information pro-
20 vided is a true and accurate copy of the appli-
21 cant’s actual tax forms as submitted to the In-
22 ternal Revenue Service.

23 “(C) REDUCED FEES.—Where the Sec-
24 retary finds that the applicant involved meets
25 the definition under subparagraph (A), the fees



1 established under subsection (c)(5) may be paid
2 at reduced rates as follows:

3 “(i) 38 percent of the fee established
4 under subsection (c)(5) for a premarket
5 application, a premarket report, a panel-
6 track supplement, or an efficacy supple-
7 ment.

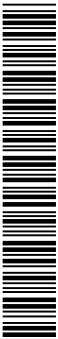
8 “(ii) 44 percent of the fee established
9 under subsection (c)(5) for a 180-day sup-
10 plement to a medical device application.

11 “(iii) 25 percent of the fee established
12 under subsection (c)(5) for a real-time sup-
13 plement to a premarket application.

14 This subsection may not be construed as au-
15 thorizing any reduction in the fee established
16 under subsection (c)(5) for a premarket notifi-
17 cation submission.

18 “(D) REQUEST FOR FEE WAIVER OR RE-
19 Duction.—An applicant seeking a fee waiver
20 or reduction under this subsection shall submit
21 supporting information to the Secretary at least
22 60 days before the fee is required pursuant to
23 subsection (a).

24 “(e) EFFECT OF FAILURE TO PAY FEES.—A pre-
25 market application, premarket report, supplement, or pre-



1 market notification submission submitted by a person sub-
2 ject to fees under subsection (a) shall be considered incom-
3 plete and shall not be accepted for filing by the Secretary
4 until all fees owed by such person have been paid.

5 “(f) CONDITIONS.—

6 “(1) PERFORMANCE GOALS THROUGH FISCAL
7 YEAR 2005; TERMINATION OF PROGRAM AFTER FIS-
8 CAL YEAR 2005.—With respect to the amount that,
9 under the salaries and expenses account of the Food
10 and Drug Administration, is appropriated for a fis-
11 cal year for devices and radiological products:

12 “(A)(i) For each of the fiscal years 2003
13 and 2004, the Secretary is expected to meet all
14 of the goals identified for the fiscal year in-
15 volved in any letter referred to in section
16 101(3) of the Medical Device User Fee and
17 Modernization Act of 2002 (referred to in this
18 paragraph as ‘performance goals’) if the
19 amount so appropriated for such fiscal year, ex-
20 cluding the amount of fees appropriated for
21 such fiscal year, is equal to or greater than
22 \$205,720,000 multiplied by the adjustment fac-
23 tor applicable to the fiscal year.

24 “(ii) For each of the fiscal years 2003 and
25 2004, if the amount so appropriated for the fis-

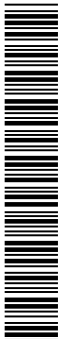


1 cal year involved, excluding the amount of fees
2 appropriated for such fiscal year, is less than
3 the amount that applies under clause (i) for
4 such fiscal year, the following applies:

5 “(I) The Secretary is expected to meet
6 such goals to the extent practicable, taking
7 into account the amounts that are avail-
8 able to the Secretary for such purpose,
9 whether from fees under subsection (a) or
10 otherwise.

11 “(II) The Comptroller General of the
12 United States shall submit to the Congress
13 a report describing whether and to what
14 extent the Secretary is meeting the per-
15 formance goals identified for such fiscal
16 year, and whether the Secretary will be
17 able to meet all performance goals identi-
18 fied for fiscal year 2005. A report under
19 the preceding sentence shall be submitted
20 to the Congress not later than July 1 of
21 the fiscal year with which the report is
22 concerned.

23 “(B)(i) For fiscal year 2005, the Secretary
24 is expected to meet all of the goals identified for
25 the fiscal year if the total of the amounts so ap-



1 appropriated for fiscal years 2003 through 2005,
2 excluding the amount of fees appropriated for
3 such fiscal years, is equal to or greater than the
4 sum of—

5 “(I) \$205,720,000 multiplied by
6 the adjustment factor applicable to
7 fiscal year 2003;

8 “(II) \$205,720,000 multiplied by
9 the adjustment factor applicable to
10 fiscal year 2004; and

11 “(III) \$205,720,000 multiplied
12 by the adjustment factor applicable to
13 fiscal year 2005.

14 “(ii) For fiscal year 2005, if the total of
15 the amounts so appropriated for fiscal years
16 2003 through 2005, excluding the amount of
17 fees appropriated for such fiscal years, is less
18 than the sum that applies under clause (i) for
19 fiscal year 2005, the following applies:

20 “(I) The Secretary is expected to
21 meet such goals to the extent prac-
22 ticable, taking into account the
23 amounts that are available to the Sec-
24 retary for such purpose, whether from
25 fees under subsection (a) or otherwise.

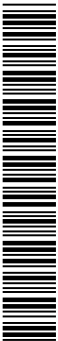


1 “(II) The Comptroller General of the
2 United States shall submit to the Congress
3 a report describing whether and to what
4 extent the Secretary is meeting the per-
5 formance goals identified for such fiscal
6 year, and whether the Secretary will be
7 able to meet all performance goals identi-
8 fied for fiscal year 2006. The report under
9 the preceding sentence shall be submitted
10 to the Congress not later than July 1,
11 2005.

12 “(C) For fiscal year 2006, fees may not be
13 assessed under subsection (a) for the fiscal
14 year, and the Secretary is not expected to meet
15 any performance goals identified for the fiscal
16 year, if the total of the amounts so appro-
17 priated for fiscal years 2003 through 2006, ex-
18 cluding the amount of fees appropriated for
19 such fiscal years, is less than the sum of—

20 “(i) \$205,720,000 multiplied by the
21 adjustment factor applicable to fiscal year
22 2006; and

23 “(ii) an amount equal to the sum that
24 applies for purposes of subparagraph
25 (B)(i).

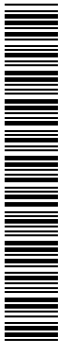


1 “(D) For fiscal year 2007, fees may not be
2 assessed under subsection (a) for the fiscal
3 year, and the Secretary is not expected to meet
4 any performance goals identified for the fiscal
5 year, if—

6 “(i) the amount so appropriated for
7 the fiscal year, excluding the amount of
8 fees appropriated for the fiscal year, is less
9 than \$205,720,000 multiplied by the ad-
10 justment factor applicable to fiscal year
11 2007; or

12 “(ii) pursuant to subparagraph (C),
13 fees were not assessed under subsection (a)
14 for fiscal year 2006.

15 “(2) AUTHORITY.—If the Secretary does not
16 assess fees under subsection (a) during any portion
17 of a fiscal year because of subparagraph (C) or (D)
18 of paragraph (1) and if at a later date in such fiscal
19 year the Secretary may assess such fees, the Sec-
20 retary may assess and collect such fees, without any
21 modification in the rate for premarket applications,
22 supplements, premarket reports, and premarket no-
23 tification submissions, and at any time in such fiscal
24 year, notwithstanding the provisions of subsection
25 (a) relating to the date fees are to be paid.



1 “(g) CREDITING AND AVAILABILITY OF FEES.—

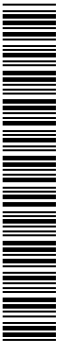
2 “(1) IN GENERAL.—Fees authorized under sub-
3 section (a) shall be collected and available for obliga-
4 tion only to the extent and in the amount provided
5 in advance in appropriation Acts. Such fees are au-
6 thorized to be appropriated to remain available until
7 expended. Such sums as may be necessary may be
8 transferred from the Food and Drug Administration
9 salaries and expenses appropriation account without
10 fiscal year limitation to such appropriation account
11 for salaries and expenses with such fiscal year limi-
12 tation. The sums transferred shall be available solely
13 for the process for the review of device applications.

14 “(2) COLLECTIONS AND APPROPRIATION
15 ACTS.—

16 “(A) IN GENERAL.—The fees authorized
17 by this section—

18 “(i) shall be retained in each fiscal
19 year in an amount not to exceed the
20 amount specified in appropriation Acts, or
21 otherwise made available for obligation, for
22 such fiscal year, and

23 “(ii) shall only be collected and avail-
24 able to defray increases in the costs of the
25 resources allocated for the process for the

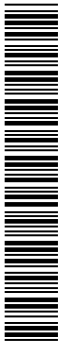


1 review of device applications (including in-
2 creases in such costs for an additional
3 number of full-time equivalent positions in
4 the Department of Health and Human
5 Services to be engaged in such process)
6 over such costs, excluding costs paid from
7 fees collected under this section, for fiscal
8 year 2002 multiplied by the adjustment
9 factor.

10 “(B) COMPLIANCE.—The Secretary shall
11 be considered to have met the requirements of
12 subparagraph (A)(ii) in any fiscal year if the
13 costs funded by appropriations and allocated for
14 the process for the review of device
15 applications—

16 “(i) are not more than 3 percent
17 below the level specified in subparagraph
18 (A)(ii); or

19 “(ii)(I) are more than 3 percent below
20 the level specified in subparagraph (A)(ii),
21 and fees assessed for a subsequent fiscal
22 year are decreased by the amount in excess
23 of 3 percent by which such costs fell below
24 the level specified in such subparagraph;
25 and



1 “(II) such costs are not more than 5
2 percent below the level specified in such
3 subparagraph.

4 “(3) AUTHORIZATION OF APPROPRIATIONS.—
5 There are authorized to be appropriated for fees
6 under this section—

7 “(A) \$25,125,000 for fiscal year 2003;

8 “(B) \$27,255,000 for fiscal year 2004;

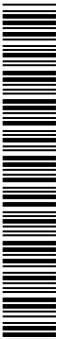
9 “(C) \$29,785,000 for fiscal year 2005;

10 “(D) \$32,615,000 for fiscal year 2006;

11 and

12 “(E) \$35,000,000 for fiscal year 2007,
13 as adjusted to reflect adjustments in the total fee
14 revenues made under this section and changes in the
15 total amounts collected by application fees.

16 “(4) OFFSET.—Any amount of fees collected
17 for a fiscal year under this section that exceeds the
18 amount of fees specified in appropriation Acts for
19 such fiscal year shall be credited to the appropria-
20 tion account of the Food and Drug Administration
21 as provided in paragraph (1), and shall be sub-
22 tracted from the amount of fees that would other-
23 wise be authorized to be collected under this section
24 pursuant to appropriation Acts for a subsequent fis-
25 cal year.



1 “(h) COLLECTION OF UNPAID FEES.—In any case
2 where the Secretary does not receive payment of a fee as-
3 sessed under subsection (a) within 30 days after it is due,
4 such fee shall be treated as a claim of the United States
5 Government subject to subchapter II of chapter 37 of title
6 31, United States Code.

7 “(i) WRITTEN REQUESTS FOR REFUNDS.—To qual-
8 ify for consideration for a refund under subsection
9 (a)(1)(D), a person shall submit to the Secretary a written
10 request for such refund not later than 180 days after such
11 fee is due.

12 “(j) CONSTRUCTION.—This section may not be con-
13 strued to require that the number of full-time equivalent
14 positions in the Department of Health and Human Serv-
15 ices, for officers, employees, and advisory committees not
16 engaged in the process of the review of device applications,
17 be reduced to offset the number of officers, employees, and
18 advisory committees so engaged.”.

19 (b) FEE EXEMPTION FOR CERTAIN ENTITIES SUB-
20 MITTING PREMARKET REPORTS.—

21 (1) IN GENERAL.—A person submitting a pre-
22 market report to the Secretary of Health and
23 Human Services is exempt from the fee under sec-
24 tion 738(a)(1)(A)(ii) of the Federal Food, Drug, and



1 Cosmetic Act (as added by subsection (a) of this sec-
2 tion) if—

3 (A) the premarket report is the first such
4 report submitted to the Secretary by the per-
5 son; and

6 (B) before October 1, 2002, the person
7 submitted a premarket application to the Sec-
8 retary for the same device as the device for
9 which the person is submitting the premarket
10 report.

11 (2) DEFINITIONS.—For purposes of paragraph
12 (1), the terms “device”, “premarket application”,
13 and “premarket report” have the same meanings as
14 apply to such terms for purposes of section 738 of
15 the Federal Food, Drug, and Cosmetic Act (as
16 added by subsection (a) of this section).

17 **SEC. 103. ANNUAL REPORTS.**

18 Beginning with fiscal year 2003, the Secretary shall
19 prepare and submit to the Committee on Energy and
20 Commerce of the House of Representatives and the Com-
21 mittee on Health, Education, Labor and Pensions of the
22 Senate a report concerning—

23 (1) the progress of the Food and Drug Admin-
24 istration in achieving the goals identified in the let-
25 ters described in section 101(3) during such fiscal



1 year and the future plans of the Food and Drug Ad-
2 ministration for meeting the goals, not later than 60
3 days after the end of each fiscal year during which
4 fees are collected under this part; and

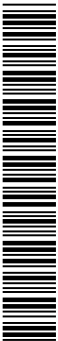
5 (2) the implementation of the authority for
6 such fees during such fiscal year, and the use, by
7 the Food and Drug Administration, of the fees col-
8 lected during such fiscal year, not later than 120
9 days after the end of each fiscal year during which
10 fees are collected under the medical device user-fee
11 program established under the amendment made by
12 section 102.

13 **SEC. 104. POSTMARKET SURVEILLANCE.**

14 (a) **ADDITIONAL AUTHORIZATION OF APPROPRIA-**
15 **TIONS.**—For the purpose of carrying out postmarket sur-
16 veillance of medical devices, there are authorized to be ap-
17 propriated to the Food and Drug Administration the fol-
18 lowing amounts, stated as increases above the amount ob-
19 ligated for such purpose by such Administration for fiscal
20 year 2002:

21 (1) For fiscal year 2003, an increase of
22 \$3,000,000.

23 (2) For fiscal year 2004, an increase of
24 \$6,000,000.



1 (3) For fiscal year 2005 and each subsequent
2 fiscal year, an increase of such sums as may be nec-
3 essary.

4 (b) STUDY.—

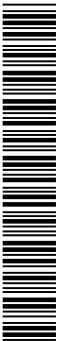
5 (1) IN GENERAL.—The Secretary of Health and
6 Human Services (referred to in this section as the
7 “Secretary”) shall conduct a study for the purpose
8 of determining the following with respect to the
9 medical device user-fee program established under
10 the amendment made by section 102:

11 (A) The impact of such program on the
12 ability of the Food and Drug Administration to
13 conduct postmarket surveillance on medical de-
14 vices.

15 (B) The programmatic improvements, if
16 any, needed for adequate postmarket surveil-
17 lance of medical devices.

18 (C) The amount of funds needed to con-
19 duct adequate postmarket surveillance of med-
20 ical devices.

21 (D) The extent to which device companies
22 comply with the postmarket surveillance re-
23 quirements, including postmarket study com-
24 mitments.

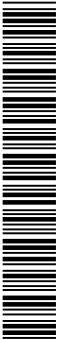


1 (E) The recommendations of the Secretary
2 as to whether, and in what amounts, user fees
3 collected under such user-fee program should be
4 dedicated to postmarket surveillance if the pro-
5 gram is extended beyond fiscal year 2007.

6 (2) REPORT.—Not later than January 10,
7 2007, the Secretary shall submit to the Committee
8 on Energy and Commerce of the House of Rep-
9 resentatives, and the Committee on Health, Edu-
10 cation, Labor, and Pensions of the Senate, a report
11 that describes the findings of the study under para-
12 graph (1).

13 **SEC. 105. CONSULTATION.**

14 (a) IN GENERAL.—In developing recommendations to
15 the Congress for the goals and plans for meeting the goals
16 for the process for the review of medical device applica-
17 tions for fiscal years after fiscal year 2007, and for the
18 reauthorization of sections 737 and 738 of the Federal
19 Food, Drug, and Cosmetic Act, the Secretary of Health
20 and Human Services (referred to in this section as the
21 “Secretary”) shall consult with the Committee on Energy
22 and Commerce of the House of Representatives, the Com-
23 mittee on Health, Education, Labor, and Pensions of the
24 Senate, appropriate scientific and academic experts,



1 health care professionals, representatives of patient and
2 consumer advocacy groups, and the regulated industry.

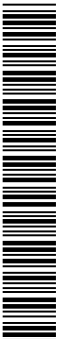
3 (b) RECOMMENDATIONS.—The Secretary shall pub-
4 lish in the Federal Register recommendations under sub-
5 section (a), after negotiations with the regulated industry;
6 shall present such recommendations to the congressional
7 committees specified in such paragraph; shall hold a meet-
8 ing at which the public may present its views on such rec-
9 ommendations; and shall provide for a period of 30 days
10 for the public to provide written comments on such rec-
11 ommendations.

12 **SEC. 106. EFFECTIVE DATE.**

13 The amendments made by this title shall take effect
14 on the date of the enactment of this Act, except that fees
15 shall be assessed for all premarket applications, premarket
16 reports, supplements, and premarket notification submis-
17 sions received on or after October 1, 2002, regardless of
18 the date of enactment.

19 **SEC. 107. SUNSET CLAUSE.**

20 The amendments made by this title cease to be effec-
21 tive October 1, 2007, except that section 103 with respect
22 to annual reports ceases to be effective January 31, 2008.



1 **TITLE II—AMENDMENTS RE-**
2 **GARDING REGULATION OF**
3 **MEDICAL DEVICES**

4 **SEC. 201. INSPECTIONS BY ACCREDITED PERSONS.**

5 (a) IN GENERAL.—Section 704 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 374) is amended by
7 adding at the end the following subsection:

8 “(g)(1) Not later than one year after the date of the
9 enactment of this subsection, the Secretary shall, subject
10 to the provisions of this subsection, accredit persons who
11 are not Federal employees for the purpose of conducting
12 the inspections required in section 510(h), or pursuant to
13 section 510(i), for establishments that manufacture, pre-
14 pare, propagate, compound, or process class II or class
15 III devices. The owner or operator of such an establish-
16 ment that is eligible under paragraph (6) may, from the
17 list published under paragraph (4), select an accredited
18 person to conduct such inspections

19 “(2) Not later than 180 days after the date of enact-
20 ment of this subsection, the Secretary shall publish in the
21 Federal Register criteria to accredit or deny accreditation
22 to persons who request to perform the duties specified in
23 paragraph (1). Thereafter, the Secretary shall inform
24 those requesting accreditation, within 60 days after the
25 receipt of such request, whether the request for accredita-

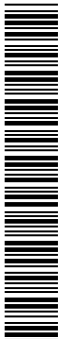


tion is adequate for review, and the Secretary shall promptly act on the request for accreditation. Any resulting accreditation shall state that such person is accredited to conduct inspections at establishments identified in paragraph (1). The accreditation of such person shall specify the particular activities under this subsection for which such person is accredited. In the first year following the publication in the Federal Register of criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1), the Secretary shall accredit no more than 15 persons who request to perform duties specified in paragraph (1).

“(3) An accredited person shall, at a minimum, meet the following requirements:

“(A) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this Act and which has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

“(B) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.



1 “(C) Such person shall not engage in the de-
2 sign, manufacture, promotion, or sale of articles reg-
3 ulated under this Act.

4 “(D) The operations of such person shall be in
5 accordance with generally accepted professional and
6 ethical business practices, and such person shall
7 agree in writing that at a minimum the person
8 will—

9 “(i) certify that reported information accu-
10 rately reflects data reviewed;

11 “(ii) limit work to that for which com-
12 petence and capacity are available;

13 “(iii) treat information received, records,
14 reports, and recommendations as confidential
15 commercial or financial information or trade se-
16 cret information;

17 “(iv) promptly respond and attempt to re-
18 solve complaints regarding its activities for
19 which it is accredited; and

20 “(v) protect against the use, in carrying
21 out paragraph (1), of any officer or employee of
22 the accredited person who has a financial con-
23 flict of interest regarding any product regulated
24 under this Act, and annually make available to
25 the public disclosures of the extent to which the

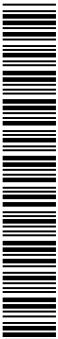


1 accredited person, and the officers and employ-
2 ees of the person, have maintained compliance
3 with requirements under this clause relating to
4 financial conflicts of interest.

5 “(4) The Secretary shall publish on the Internet site
6 of the Food and Drug Administration a list of accredited
7 persons to conduct inspections under paragraph (1). Such
8 list shall be periodically updated to ensure that the iden-
9 tity of each accredited person is known to the public. The
10 updating of such list shall be no later than one month
11 after the accreditation of a person under this subsection
12 or the withdrawal of accreditation.

13 “(5)(A) To ensure that persons accredited under this
14 subsection continue to meet the standards of accredita-
15 tion, the Secretary shall audit the performance of such
16 persons on a periodic basis through the review of inspec-
17 tion reports and inspections by persons designated by the
18 Secretary to evaluate the compliance status of an estab-
19 lishment and the performance of accredited persons.

20 “(B) The Secretary may withdraw accreditation of
21 any person accredited under paragraph (2), after pro-
22 viding notice and an opportunity for an informal hearing,
23 when such person is substantially not in compliance with
24 the standards of accreditation or poses a threat to public
25 health or fails to act in a manner that is consistent with



1 the purposes of this subsection. The Secretary may sus-
2 pend the accreditation of such person during the pendency
3 of the process under the preceding sentence.

4 “(6)(A) Subject to subparagraphs (B) through (C),
5 a device establishment is eligible for inspections by persons
6 accredited under paragraph (2) if—

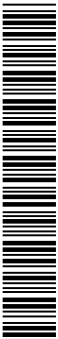
7 “(i) the Secretary classified the results of the
8 most recent inspection of the establishment pursuant
9 to subsection (h) or (i) of section 510 as ‘no action
10 indicated’ or ‘voluntary action indicated’; and

11 “(ii) with respect to each inspection to be con-
12 ducted by an accredited person—

13 “(I) the owner or operator of the establish-
14 ment submits to the Secretary a notice request-
15 ing clearance to use such a person to conduct
16 the inspection, and the Secretary provides such
17 clearance; and

18 “(II) such notice identifies the accredited
19 person whom the establishment has selected to
20 conduct the inspection, and the Secretary
21 agrees to the selected accredited person.

22 “(B)(i) The Secretary shall respond to a notice under
23 subparagraph (A) from an establishment not later than
24 30 days after the Secretary receives the notice. Through
25 such response, the Secretary shall (I) provide clearance



1 under such subparagraph, and agree to the selection of
2 an accredited person, or (II) make a request under clause
3 (ii). If the Secretary fails to respond to the notice within
4 such 30-day period, the establishment is deemed to have
5 such clearance, and to have the agreement of the Sec-
6 retary for such selection.

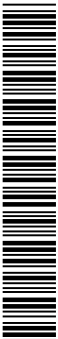
7 “(ii) The request referred to in clause (i)(II) is—

8 “(I) a request to the establishment involved to
9 submit to the Secretary compliance data in accord-
10 ance with clause (iii); or

11 “(II) a request to the establishment, or to the
12 accredited person identified in the notice under sub-
13 paragraph (A), for information concerning the rela-
14 tionship between the establishment and such accred-
15 ited person.

16 The Secretary may make both such requests.

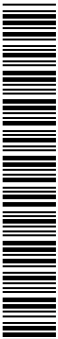
17 “(iii) The compliance data to be submitted by an es-
18 tablishment under clause (ii) are data describing whether
19 the quality controls of the establishment have been suffi-
20 cient for ensuring consistent compliance with current good
21 manufacturing practice within the meaning of section
22 501(h), and data otherwise describing whether the estab-
23 lishment has consistently been in compliance with sections
24 501 and 502 and other applicable provisions of this Act.
25 Such data shall include complete reports of inspections re-



1 garding good manufacturing practice or other quality con-
2 trol audits that, during the preceding two-year period,
3 were conducted at the establishment by persons other than
4 the owner or operator of the establishment, together with
5 all other data the Secretary deems necessary. Data under
6 the preceding sentence shall demonstrate to the Secretary
7 whether the establishment has facilitated consistent com-
8 pliance by promptly correcting any compliance problems
9 identified in such inspections.

10 “(iv) Not later than 60 days after receiving compli-
11 ance data under clause (iii) from an establishment, the
12 Secretary shall provide or deny clearance under subpara-
13 graph (A). The Secretary may not deny clearance unless
14 the Secretary provides to the establishment detailed find-
15 ings that the establishment has failed to demonstrate con-
16 sistent compliance for purposes of clause (iii). If the Sec-
17 retary fails to provide such findings to the establishment
18 within such 60-day period, the establishment is deemed
19 to have such clearance.

20 “(v)(I) A request to an accredited person under
21 clause (ii)(II) may not seek any information that is not
22 required to be maintained by such person in records under
23 subsection (f)(1). Not later than 60 days after receiving
24 the information sought by the request, the Secretary shall
25 agree to, or reject, the selection of such person by the es-



1 establishment involved. The Secretary may not reject the se-
2 lection unless the Secretary provides to the establishment
3 the reasons for such rejection. Reasons for the rejection
4 may include that the establishment or the accredited per-
5 son, as the case may be, has failed to fully respond to
6 the request. If within such 60-day period the Secretary
7 fails to agree to or reject the selection in accordance with
8 this subclause, the Secretary is deemed to have agreed to
9 the selection.

10 “(II) If the Secretary rejects the selection of an ac-
11 credited person by an establishment, the establishment
12 may make an additional selection of an accredited person
13 by submitting to the Secretary a notice that identifies the
14 additional selection. Clauses (i) and (ii), and subclause (I)
15 of this clause, apply to the selection of an accredited per-
16 son through a notice under the preceding sentence in the
17 same manner and to the same extent as such provisions
18 apply to a selection of an accredited person through a no-
19 tice under subparagraph (A).

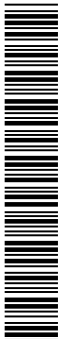
20 “(vi) In the case of an establishment that under
21 clause (iv) is denied clearance under subparagraph (A),
22 or whose selection of an accredited person is rejected
23 under clause (v), the Secretary shall designate a person
24 to review the findings of the Secretary under such clause
25 if, during the 30-day period beginning on the date on



1 which the establishment receives the findings, the estab-
2 lishment requests the review. The review shall commence
3 not later than 30 days after the establishment requests
4 the review, unless the Secretary and the establishment
5 otherwise agree.

6 “(C)(i) In the case of a device establishment for
7 which the Secretary classified the results of the most re-
8 cent inspection of the establishment by a person accredited
9 under paragraph (2) as ‘official action indicated’, the es-
10 tablishment is eligible for further inspections by persons
11 accredited under such paragraph if (I) the Secretary
12 issues a written statement to the owner or operator of the
13 establishment that the violations leading to such classifica-
14 tion have been resolved, and (II) the Secretary, either
15 upon the Secretary’s own initiative or a petition of the
16 owner or operator of the establishment, notifies the estab-
17 lishment that it has clearance to use an accredited person
18 for the inspections. The Secretary shall respond to such
19 petition within 30 days after the receipt of the petition.

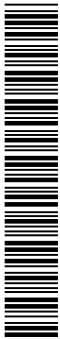
20 “(ii) If the Secretary denies a petition under clause
21 (i), the establishment involved may, after the expiration
22 of one year after such denial, again petition the Secretary
23 for a determination of eligibility for inspection by persons
24 accredited by the Secretary under paragraph (2). If the
25 Secretary denies such petition, the Secretary shall provide



1 the establishment with a detailed reason for such denial
2 within 60 days after the denial. If, as of the expiration
3 of 48 months after the receipt of the first petition, the
4 establishment has not been inspected by the Secretary in
5 accordance with section 510(h), or has not during such
6 period been inspected pursuant to section 510(i), as appli-
7 cable, the establishment is eligible for further inspections
8 by accredited persons.

9 “(7)(A) Persons accredited under paragraph (2) to
10 conduct inspections shall record in writing their inspection
11 observations and shall present the observations to the de-
12 vice establishment’s designated representative and discuss
13 each observation. Additionally, such accredited person
14 shall prepare an inspection report (including for inspec-
15 tions classified as ‘no action indicated’) in a form and
16 manner consistent with such reports prepared by employ-
17 ees and officials designated by the Secretary to conduct
18 inspections.

19 “(B) At a minimum, an inspection report under sub-
20 paragraph (A) shall identify the persons responsible for
21 good manufacturing practice compliance at the inspected
22 establishment involved, the dates of the inspection, the
23 scope of the inspection, and shall discuss in detail each
24 observation identified by the accredited person, identify
25 other matters that relate to or may influence compliance



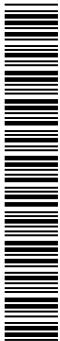
1 with this Act, and discuss any recommendations during
2 the inspection or at the inspection's closing meeting.

3 “(C) An inspection report under subparagraph (A)
4 shall be sent to the Secretary and the designated rep-
5 resentative of the inspected establishment involved at the
6 same time, but under no circumstances later than three
7 weeks after the last day of the inspection. The report to
8 the Secretary shall be accompanied by all written inspec-
9 tion observations previously provided to the representative
10 of the establishment.

11 “(D) Any statements or representations made by em-
12 ployees or agents of a device establishment to persons ac-
13 credited under paragraph (2) to conduct inspections shall
14 be subject to section 1001 of title 18, United States Code.

15 “(E) If at any time during an inspection by an ac-
16 credited person the accredited person discovers a condition
17 that could cause or contribute to an unreasonable risk to
18 the public health, the accredited person shall immediately
19 notify the Secretary of the identification of the facility
20 subject to inspection and the conditions of concern.

21 “(8) Compensation for an accredited person shall be
22 determined by agreement between the accredited person
23 and the person who engages the services of the accredited
24 person, and shall be paid by the person who engages such
25 services.



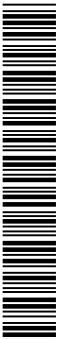
1 “(9) Nothing in this subsection affects the authority
2 of the Secretary to inspect establishments pursuant to this
3 Act.

4 “(10)(A) For fiscal year 2005 and subsequent fiscal
5 years, no device establishment may be inspected during
6 the fiscal year involved by a person accredited under para-
7 graph (2) if—

8 “(i) of the amounts appropriated for salaries
9 and expenses of the Food and Drug Administration
10 for the preceding fiscal year (referred to in this sub-
11 paragraph as the ‘first prior fiscal year’), the
12 amount obligated by the Secretary for inspections of
13 device establishments by the Secretary was less than
14 the adjusted base amount applicable to such first
15 prior fiscal year; and

16 “(ii) of the amounts appropriated for salaries
17 and expenses of the Food and Drug Administration
18 for the fiscal year preceding the first prior fiscal
19 year (referred to in this subparagraph as the ‘second
20 prior fiscal year’), the amount obligated by the Sec-
21 retary for inspections of device establishments by the
22 Secretary was less than the adjusted base amount
23 applicable to such second prior fiscal year.

24 “(B)(i) Subject to clause (ii), the Comptroller Gen-
25 eral of the United States shall determine the amount that



1 was obligated by the Secretary for fiscal year 2002 for
2 compliance activities of the Food and Drug Administra-
3 tion with respect to devices (referred to in this subpara-
4 graph as the ‘compliance budget’), and of such amount,
5 the amount that was obligated for inspections by the Sec-
6 retary of device establishments (referred to in this sub-
7 paragraph as the ‘inspection budget’).

8 “(ii) For purposes of determinations under clause (i),
9 the Comptroller General shall not include in the compli-
10 ance budget or the inspection budget any amounts obli-
11 gated for inspections of device establishments conducted
12 as part of the process of reviewing applications under sec-
13 tion 515.

14 “(iii) Not later than March 31, 2003, the Comptroller
15 General shall complete the determinations required in this
16 subparagraph and submit to the Secretary and the Con-
17 gress a reporting describing the findings made through
18 such determinations.

19 “(C) For purposes of this paragraph:

20 “(i) The term ‘base amount’ means the inspec-
21 tion budget determined under subparagraph (B) for
22 fiscal year 2002.

23 “(ii) The term ‘adjusted base amount’, in the
24 case of applicability to fiscal year 2003, means an



1 amount equal to the base amount increased by 5
2 percent.

3 “(iii) The term ‘adjusted base amount’, with re-
4 spect to applicability to fiscal year 2004 or any sub-
5 sequent fiscal year, means the adjusted based
6 amount applicable to the preceding year increased by
7 5 percent.

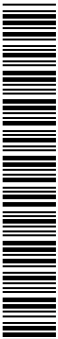
8 “(11) The authority provided by this subsection ter-
9 minates on October 1, 2012.

10 “(12) No later than four years after the enactment
11 of this subsection the Comptroller General shall report to
12 the Committee on Energy and Commerce of the House
13 of Representatives and the Committee on Health, Edu-
14 cation, Labor and Pensions of the Senate—

15 “(A) the number of inspections conducted by
16 accredited persons and the number of inspections
17 pursuant to subsections (h) and (i) of section 510
18 conducted by Federal employees;

19 “(B) the number of persons who sought accred-
20 itation under this subsection, as well as the number
21 of persons who were accredited under this sub-
22 section;

23 “(C) the reasons why persons who sought ac-
24 creditation, but were denied accreditation, were de-
25 nied;



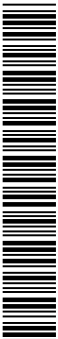
1 “(D) the number of audits conducted by the
2 Secretary of accredited persons, the quality of in-
3 spections conducted by accredited persons, whether
4 accredited persons are meeting their obligations
5 under this Act, and whether the number of audits
6 conducted is sufficient to permit these assessments;

7 “(E) whether this subsection is achieving the
8 goal of ensuring more information about establish-
9 ment compliance is being presented to the Secretary,
10 and whether that information is of a quality con-
11 sistent with information obtained by the Secretary
12 pursuant to subsection (h) or (i) of section 510;

13 “(F) whether this subsection is advancing ef-
14 forts to allow device establishments to rely upon
15 third-party inspections for purposes of compliance
16 with the laws of foreign governments; and

17 “(G) whether the Congress should continue,
18 modify, or terminate the program under this sub-
19 section.

20 “(13) The Secretary shall include in the annual re-
21 port required under section 903(g) the names of all ac-
22 credited persons and the particular activities under this
23 subsection for which each such person is accredited and
24 the name of each accredited person whose accreditation
25 has been withdrawn during the year.”.



1 (b) MAINTENANCE OF RECORDS.—Section 704(f) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 374(f)) is amended—

4 (1) in paragraph (1), in the first sentence, by
5 striking “A person accredited” and all that follows
6 through “shall maintain records” and inserting the
7 following: “An accredited person described in para-
8 graph (3) shall maintain records”;

9 (2) in paragraph (2), by striking “a person ac-
10 credited under section 523” and inserting “an ac-
11 credited person described in paragraph (3)”; and

12 (3) by adding at the end the following para-
13 graph:

14 “(3) For purposes of paragraphs (1) and (2), an ac-
15 credited person described in this paragraph is a person
16 who—

17 “(A) is accredited under subsection (g); or

18 “(B) is accredited under section 523.”.

19 (c) CONFORMING AMENDMENT.—Section 510(h) of
20 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
21 360(h)) is amended by inserting after “duly designated
22 by the Secretary” the following: “, or by persons accred-
23 ited to conduct inspections under section 704(g),”.



1 **SEC. 202. THIRD PARTY REVIEW OF PREMARKET NOTIFICA-**
2 **TION.**

3 Section 523 of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 360m) is amended—

5 (1) in subsection (c), by striking “The author-
6 ity” and all that follows and inserting the following:
7 “The authority provided by this section terminates
8 October 1, 2007.”; and

9 (2) by adding at the end the following sub-
10 section:

11 “(d) REPORT.—Not later than January 10, 2007, the
12 Secretary shall conduct a study based on the experience
13 under the program under this section and submit to the
14 Committee on Energy and Commerce of the House of
15 Representatives, and the Committee on Health, Edu-
16 cation, Labor, and Pensions of the Senate, a report de-
17 scribing the findings of the study. The objectives of the
18 study shall include determining—

19 “(1) the number of devices reviewed under this
20 section;

21 “(2) the number of devices reviewed under this
22 section that were ultimately cleared by the Sec-
23 retary;

24 “(3) the number of devices reviewed under this
25 section that were ultimately not cleared by the Sec-
26 retary;



1 “(4) the average time period for a review under
2 this section (including the time it takes for the Sec-
3 retary to review a recommendation of an accredited
4 person under subsection (a) and determine the ini-
5 tial device classification);

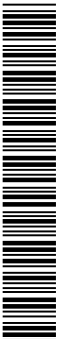
6 “(5) the average time period identified in para-
7 graph (4) compared to the average time period for
8 review of devices solely by the Secretary pursuant to
9 section 510(k);

10 “(6) if there is a difference in the average time
11 period under paragraph (4) and the average time pe-
12 riod under paragraph (5), the reasons for such dif-
13 ference;

14 “(7) whether the quality of reviews under this
15 section for devices for which no guidance has been
16 issued is qualitatively inferior to reviews by the Sec-
17 retary for devices for which no guidance has been
18 issued;

19 “(8) whether the quality of reviews under this
20 section of devices for which no guidance has been
21 issued is qualitatively inferior to reviews under this
22 section of devices for which guidance has been
23 issued;

24 “(9) whether this section has in any way jeop-
25 ardized or improved the public health;



1 “(10) any impact of this section on resources
2 available to the Secretary to review reports under
3 section 510(k); and

4 “(11) any suggestions for continuation, modi-
5 fication (including expansion of device eligibility), or
6 termination of this section that the Secretary deter-
7 mines to be appropriate.”.

8 **SEC. 203. DESIGNATION AND REGULATION OF COMBINA-**
9 **TION PRODUCTS.**

10 Section 503(g) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 353(g)) is amended—

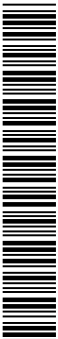
12 (1) in paragraph (1) -

13 (A) in the first sentence, by striking “shall
14 designate a component of the Food and Drug
15 Administration” and inserting “shall in accord-
16 ance with this subsection assign an agency cen-
17 ter”; and

18 (B) in each of subparagraphs (A) through
19 (C), by striking “the persons charged” and in-
20 serting “the agency center charged”;

21 (2) by redesignating paragraph (4) as para-
22 graph (5);

23 (3) by inserting after paragraph (3) the fol-
24 lowing paragraph:

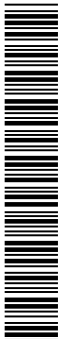


1 “(4)(A) Not later than 60 days after the date of the
2 enactment of this paragraph, the Secretary shall establish
3 within the Office of the Commissioner of Food and Drugs
4 an office to ensure the prompt assignment of combination
5 products to agency centers, the timely premarket review
6 of such products, and consistent and appropriate
7 postmarket regulation of like products subject to the same
8 statutory requirements to the extent permitted by law. Ad-
9 ditionally, the office shall, in determining whether a prod-
10 uct is to be designated a combination product, consult with
11 the component within the Office of the Commissioner of
12 Food and Drugs that is responsible for such determina-
13 tions. Such office (referred to in this paragraph as the
14 ‘Office’) shall have appropriate scientific and medical ex-
15 pertise, and shall be headed by a director.

16 “(B) In carrying out this subsection, the Office shall,
17 for each combination product, promptly assign an agency
18 center with primary jurisdiction in accordance with para-
19 graph (1) for the premarket review of such product.

20 “(C) In carrying out this subsection, the Office shall
21 ensure timely and effective premarket reviews by over-
22 seeing and coordinating reviews involving more than one
23 agency center.

24 “(D) In carrying out this subsection, the Office shall
25 ensure the consistency and appropriateness of postmarket



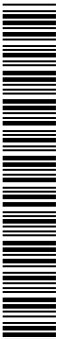
1 regulation of like products subject to the same statutory
2 requirements to the extent permitted by law. Nothing in
3 this paragraph shall be construed to limit the postmarket
4 regulatory authority of any agency center.

5 “(E) In order to ensure the timeliness of the pre-
6 market review of a combination product, the agency center
7 with primary jurisdiction for the product, and the con-
8 sulting agency center, shall be responsible to the Office
9 with respect to the timeliness of the premarket review.

10 “(F)(i) Any dispute regarding the timeliness of the
11 premarket review of a combination product may be pre-
12 sented to the Office for resolution, unless the timeliness
13 of the dispute is clearly premature.

14 “(ii) During the review process, any dispute regard-
15 ing the substance of the premarket review may be pre-
16 sented to the Commissioner of Food and Drugs after first
17 being considered by the agency center with primary juris-
18 diction of the premarket review, under the scientific dis-
19 pute resolution procedures for such center. The Commis-
20 sioner of Food and Drugs shall consult with the Director
21 of the Office in resolving the substantive dispute.

22 “(G) The Secretary, acting through the Office, shall
23 review each agreement, guidance, or practice of the Sec-
24 retary that is specific to the assignment of combination
25 products to agency centers and shall determine whether

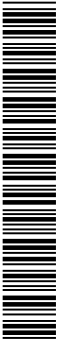


1 the agreement, guidance, or practice is consistent with the
2 requirements of this subsection. In carrying out such re-
3 view, the Secretary shall consult with stakeholders and the
4 directors of the agency centers. After such consultation,
5 the Secretary shall determine whether to continue in ef-
6 fect, modify, revise, or eliminate such agreement, guid-
7 ance, or practice, and shall publish in the Federal Register
8 a notice of the availability of such modified or revised
9 agreement, guidance or practice. Nothing in this para-
10 graph shall be construed as preventing the Secretary from
11 following each agreement, guidance, or practice until con-
12 tinued, modified, revised, or eliminated.

13 “(H) Not later than one year after the date of the
14 enactment of this paragraph and annually thereafter, the
15 Secretary shall report to the appropriate committees of
16 Congress on the activities and impact of the Office. The
17 report shall include provisions—

18 “(i) describing the numbers and types of com-
19 bination products under review and the timeliness in
20 days of such assignments, reviews, and dispute reso-
21 lutions;

22 “(ii) identifying the number of premarket re-
23 views of such products that involved a consulting
24 agency center; and



1 “(iii) describing improvements in the consist-
2 ency of postmarket regulation of combination prod-
3 ucts.”; and

4 (4) in paragraph (5) (as redesignated by para-
5 graph (2) of this section)—

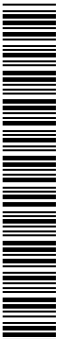
6 (A) by redesignating subparagraphs (A)
7 and (B) as subparagraphs (A) and (C), respec-
8 tively; and

9 (B) by inserting before subparagraph (B)
10 the following subparagraph:

11 “(A) The term ‘agency center’ means a center
12 or alternative organizational component of the Food
13 and Drug Administration.”.

14 **SEC. 204. REPORT ON CERTAIN DEVICES.**

15 Not later than one year after the date of enactment
16 of this Act, the Secretary of Health and Human Services
17 shall report to the appropriate committees of Congress on
18 the timeliness and effectiveness of device premarket re-
19 views by centers other than the Center for Devices and
20 Radiological Health. Such report shall include information
21 on the times required to log in and review original submis-
22 sions and supplements, times required to review manufac-
23 turers’ replies to submissions, and times to approve or
24 clear such devices. Such report shall contain the Sec-
25 retary’s recommendations on any measures needed to im-



1 prove performance including, but not limited to, the alloca-
2 tion of additional resources. Such report also shall include
3 the Secretary's specific recommendation on whether re-
4 sponsibility for regulating such devices should be reas-
5 signed to those persons within the Food and Drug Admin-
6 istration who are primarily charged with regulating other
7 types of devices, and whether such a transfer could have
8 a deleterious impact on the public health and on the safety
9 of such devices.

10 **SEC. 205. ELECTRONIC LABELING.**

11 Section 502(f) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 352(f)) is amended by adding at the
13 end the following: "Required labeling for prescription de-
14 vices intended for use in health care facilities may be made
15 available solely by electronic means provided that the la-
16 beling complies with all applicable requirements of law
17 and, that the manufacturer affords health care facilities
18 the opportunity to request the labeling in paper form, and
19 after such request, promptly provides the health care facil-
20 ity the requested information without additional cost."

21 **SEC. 206. ELECTRONIC REGISTRATION.**

22 Section 510 of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 360) is amended by adding at the end the
24 following:



1 “(p) **ELECTRONIC REGISTRATION.**—Registrations
2 under subsections (b), (c), (d), and (i) (including the sub-
3 mission of updated information) shall be submitted to the
4 Secretary by electronic means, upon a finding by the Sec-
5 retary that the electronic receipt of such registrations is
6 feasible, unless the Secretary grants a request for waiver
7 of such requirement because use of electronic means is not
8 reasonable for the person requesting such waiver.”.

9 **SEC. 207. INTENDED USE.**

10 Section 513(i)(1)(E) of the Federal Food, Drug, and
11 Cosmetic Act (21 U.S.C. 360c(i)(1)(E)) is amended by
12 striking clause (iv).

13 **SEC. 208. MODULAR REVIEW.**

14 Section 515(c) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 360e(c)) is amended by adding at
16 the end the following:

17 “(3)(A) Prior to the submission of an application
18 under this subsection, the Secretary shall accept and re-
19 view portions of such applications that applicants and the
20 Secretary agree are complete, ready, and appropriate for
21 review.

22 “(B) Each portion of a submission reviewed under
23 subparagraph (A) and found acceptable by the Secretary
24 shall not be further reviewed after receipt of an application
25 that satisfies the requirements of paragraph (1), unless



1 issues of safety or effectiveness provide the Secretary
2 cause to review such accepted portion.

3 “(C) Whenever the Secretary determines that a por-
4 tion of a submission under subparagraph (A) is unaccept-
5 able, the Secretary shall specifically identify, in writing,
6 the deficiency of such portion and describe in detail the
7 means by which it may be made acceptable, unless the
8 sponsor is no longer pursuing the application.”.

9 **SEC. 209. PEDIATRIC EXPERTISE REGARDING CLASSIFICA-**
10 **TION-PANEL REVIEW OF PREMARKET APPLI-**
11 **CATIONS.**

12 Section 515(c)(2) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 360e(c)(2)) is amended by add-
14 ing at the end the following: “If the Secretary determines
15 that there is a reasonable likelihood that the device in-
16 volved will be used in a pediatric population, the Secretary
17 shall ensure that such panel includes, or consults with, one
18 or more pediatric experts.”.

19 **SEC. 210. INTERNET LIST OF CLASS II DEVICES EXEMPTED**
20 **FROM REQUIREMENT OF PREMARKET NOTI-**
21 **FICATION.**

22 Section 510(m)(1) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 360(m)(1)) is amended by add-
24 ing at the end the following: “The Secretary shall publish
25 such list on the Internet site of the Food and Drug Ad-



1 ministration. The list so published shall be updated not
2 later than 30 days after each revision of the list by the
3 Secretary.”.

4 **SEC. 211. STUDY BY INSTITUTE OF MEDICINE OF**
5 **POSTMARKET SURVEILLANCE REGARDING**
6 **PEDIATRIC POPULATIONS.**

7 (a) IN GENERAL.—The Secretary of Health and
8 Human Services (referred to in this section as the “Sec-
9 retary”) shall request the Institute of Medicine to enter
10 into an agreement with the Secretary under which such
11 Institute conducts a study for the purpose of determining
12 whether the system under the Federal Food, Drug, and
13 Cosmetic Act for the postmarket surveillance of medical
14 devices provides adequate safeguards regarding the use of
15 devices in pediatric populations.

16 (b) CERTAIN MATTERS.—The Secretary shall ensure
17 that determinations made in the study under subsection
18 (a) include determinations of—

19 (1) whether postmarket surveillance studies of
20 implanted medical devices are of long enough dura-
21 tion to evaluate the impact of growth and develop-
22 ment for the number of years that the child will
23 have the implant, and whether the studies are ade-
24 quate to evaluate how children’s active lifestyles may



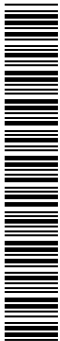
1 affect the failure rate and longevity of the implant;
2 and

3 (2) whether the amount of funds allocated for
4 postmarket surveillance by the Food and Drug Ad-
5 ministration of medical devices used in pediatric
6 populations is sufficient to provide adequate safe-
7 guards for such populations, taking into account the
8 Secretary's monitoring of commitments made at the
9 time of approval of medical devices, such as phase
10 IV trials, and the Secretary's monitoring and use of
11 adverse reaction reports, registries, and other
12 postmarket surveillance activities.

13 (c) REPORT TO CONGRESS.—The Secretary shall en-
14 sure that, not later than four years after the date of the
15 enactment of this Act, a report describing the findings of
16 the study under subsection (a) is submitted to the Con-
17 gress. The report shall include any recommendations of
18 the Secretary for administrative or legislative changes to
19 the system of postmarket surveillance referred to in such
20 subsection.

21 **SEC. 212. GUIDANCE REGARDING PEDIATRIC DEVICES.**

22 Section 520 of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 360j) is amended by adding at the end
24 the following subsection:



1 “Guidance Regarding Pediatric Devices

2 “(n) Not later than 270 days after the date of the
3 enactment of the Medical Device User Fee and Moderniza-
4 tion Act of 2002, the Secretary shall issue guidance on
5 the following:

6 “(1) The type of information necessary to pro-
7 vide reasonable assurance of the safety and effective-
8 ness of devices intended for use in pediatric popu-
9 lations.

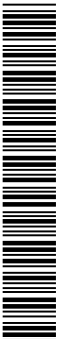
10 “(2) Protections for pediatric subjects in clin-
11 ical investigations of the safety or effectiveness of
12 such devices.”.

13 **SEC. 213. BREAST IMPLANTS; STUDY BY COMPTROLLER**
14 **GENERAL.**

15 (a) IN GENERAL.—The Comptroller General of the
16 United States shall conduct a study to determine the fol-
17 lowing with respect to breast implants:

18 (1) The content of information typically pro-
19 vided by health professionals to women who consult
20 with such professionals on the issue of whether to
21 undergo breast implant surgery.

22 (2) Whether such information is provided by
23 physicians or other health professionals, and whether
24 the information is provided verbally or in writing.



1 (3) Whether the information provided presents
2 a fair and balanced statement of the risks and bene-
3 fits of receiving the implants (taking into account
4 the frequency of updates to the information), and if
5 so, at what point in the process of determining
6 whether to undergo surgery is such information pro-
7 vided.

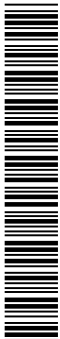
8 (4) Whether women understand the information
9 that is provided (including full appreciation of the
10 risks), and whether and to what extent the informa-
11 tion influences the decision to receive the implants.

12 (5) The number of adverse events that have
13 been reported, and whether such events have been
14 adequately investigated.

15 (6) With respect to women who participate as
16 subjects in research being carried out regarding the
17 safety and effectiveness of breast implants:

18 (A) The content of information provided to
19 the women during the process of obtaining the
20 informed consent of the women to be subjects,
21 and whether such information is appropriately
22 updated.

23 (B) Whether such process provides written
24 explanations of the criteria for being subjects in
25 the research.



1 (C) The point at which, in the planning or
2 conduct of the research, the women are pro-
3 vided information regarding the provision of in-
4 formed consent to be subjects.

5 (D) Whether, before providing informed
6 consent, the women fully appreciate the risks of
7 being subjects in the research.

8 (b) REPORT.—The Comptroller General shall submit
9 to the Congress a report describing the findings of the
10 study.

11 (c) DEFINITION.—For purposes of this section, the
12 term “breast implant” means a breast prosthesis that is
13 implanted to augment or reconstruct the female breast.

14 **SEC. 214. BREAST IMPLANTS; RESEARCH THROUGH NA-**
15 **TIONAL INSTITUTES OF HEALTH.**

16 (a) REPORT ON STATUS OF CURRENT RESEARCH.—
17 Not later than 180 days after the date of the enactment
18 of this Act, the Director of the National Institutes of
19 Health shall submit to the Congress a report describing
20 the status of research on breast implants (as defined in
21 section 213(c)) being conducted or supported by such In-
22 stitutes.

23 (b) RESEARCH ON LONG-TERM IMPLICATIONS.—
24 Part H of title IV of the Public Health Service Act (42



1 U.S.C. 289 et seq.) is amended by adding at the end of
2 the following section:

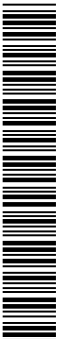
3 **“SEC. 498C. BREAST IMPLANT RESEARCH.**

4 “(a) IN GENERAL.—The Director of NIH shall con-
5 duct or support prospective or retrospective research to
6 examine the long-term health implications of both saline
7 and silicone breast implants. If scientifically appropriate,
8 such research studies may include the following:

9 “(1) A multidisciplinary study of women who
10 have received silicone and saline implants and have
11 had an implant for a sufficient amount of time to
12 allow for appropriate comparison as to the long-term
13 health consequences.

14 “(2) A comparison of women receiving implants
15 for reconstruction after mastectomy to breast cancer
16 patients who have not had reconstruction, including
17 subsets of women with saline implants and women
18 with silicone implants.

19 “(b) DEFINITION.—For purposes of this section, the
20 term ‘breast implant’ means a breast prosthesis that is
21 implanted to augment or reconstruct the female breast.”.



1 **TITLE III—ADDITIONAL**
2 **AMENDMENTS**

3 **SEC. 301. IDENTIFICATION OF MANUFACTURER OF MED-**
4 **ICAL DEVICES.**

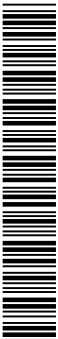
5 (a) IN GENERAL.—Section 502 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 352) is amended by
7 adding at the end the following:

8 “(u) If it is a device, unless it, or an attachment
9 thereto, prominently and conspicuously bears the name of
10 the manufacturer of the device, a generally recognized ab-
11 breviation of such name, or a unique and generally recog-
12 nized symbol identifying such manufacturer, except that
13 the Secretary may waive any requirement under this para-
14 graph for the device if the Secretary determines that com-
15 pliance with the requirement is not feasible for the device
16 or would compromise the provision of reasonable assur-
17 ance of the safety or effectiveness of the device.”.

18 (b) EFFECTIVE DATE.—The amendment made by
19 subsection (a) takes effect 18 months after the date of
20 the enactment of this Act, and only applies to devices in-
21 troduced or delivered for introduction into interstate com-
22 merce after such effective date.

23 **SEC. 302. SINGLE-USE MEDICAL DEVICES.**

24 (a) REQUIRED STATEMENTS ON LABELING.—



1 (1) IN GENERAL.—Section 502 of the Federal
2 Food, Drug, and Cosmetic Act, as amended by sec-
3 tion 301 of this Act, is amended by adding at the
4 end the following:

5 “(v) If it is a reprocessed single-use device, unless
6 all labeling of the device prominently and conspicuously
7 bears the statement ‘Reprocessed device for single use. Re-
8 processed by ____.’ The name of the manufacturer of the
9 reprocessed device shall be placed in the space identifying
10 the person responsible for reprocessing.”.

11 (2) EFFECTIVE DATE.—The amendment made
12 by paragraph (1) takes effect 15 months after the
13 date of the enactment of this Act, and only applies
14 to devices introduced or delivered for introduction
15 into interstate commerce after such effective date.

16 (b) PREMARKET NOTIFICATION.—Section 510 of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360)
18 is amended by inserting after subsection (n) the following:

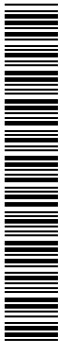
19 “(o)(1) With respect to reprocessed single-use devices
20 for which reports are required under subsection (k):

21 “(A) The Secretary shall identify such devices
22 or types of devices for which reports under such sub-
23 section must, in order to ensure that the device is
24 substantially equivalent to a predicate device, include
25 validation data, the types of which shall be specified



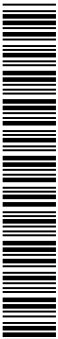
1 by the Secretary, regarding cleaning and steriliza-
2 tion, and functional performance demonstrating that
3 the single-use device will remain substantially equiv-
4 alent to its predicate device after the maximum
5 number of times the device is reprocessed as in-
6 tended by the person submitting the premarket noti-
7 fication. Within one year after enactment of this
8 subsection, the Secretary shall publish in the Fed-
9 eral Register a list of the types so identified, and
10 shall revise the list as appropriate. Reports under
11 subsection (k) for devices or types of devices within
12 a type included on the list are, upon publication of
13 the list, required to include such validation data.

14 “(B) In the case of each report under sub-
15 section (k) that was submitted to the Secretary be-
16 fore the publication of the initial list under subpara-
17 graph (A), or any revision thereof, and was for a de-
18 vice or type of device included on such list, the per-
19 son who submitted the report under subsection (k)
20 shall submit validation data as described in subpara-
21 graph (A) to the Secretary not later than nine
22 months after the publication of the list. During such
23 nine-month period, the Secretary may not take any
24 action under this Act against such device solely on
25 the basis that the validation data for the device have



1 not been submitted to the Secretary. After the sub-
2 mission of the validation data to the Secretary, the
3 Secretary may not determine that the device is mis-
4 branded under section 502(o), adulterated under
5 section 501(f)(1)(B), or take action against the de-
6 vice under section 301(p) for failure to provide any
7 information required by subsection (k) until (i) the
8 review is terminated by withdrawal of the submis-
9 sion of the report under subsection (k); (ii) the Sec-
10 retary finds the data to be acceptable and issues a
11 letter; or (iii) the Secretary determines that the de-
12 vice is not substantially equivalent to a predicate de-
13 vice. Upon a determination that a device is not sub-
14 stantially equivalent to a predicate device, or if such
15 submission is withdrawn, the device can no longer be
16 legally marketed.

17 “(C) In the case of a report under subsection
18 (k) for a device identified under subparagraph (A)
19 that is of a type for which the Secretary has not
20 previously received a report under such subsection,
21 the Secretary may, in advance of revising the list
22 under subparagraph (A) to include such type, re-
23 quire that the report include the validation data
24 specified in subparagraph (A).

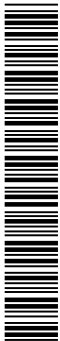


1 “(D) Section 502(o) applies with respect to the
2 failure of a report under subsection (k) to include
3 validation data required under subparagraph (A).

4 “(2) With respect to critical or semicritical repro-
5 essed single-use devices that, under subsection (l) or (m),
6 are exempt from the requirement of submitting reports
7 under subsection (k):

8 “(A) The Secretary shall identify such devices
9 or types of devices for which such exemptions should
10 be terminated in order to provide a reasonable as-
11 surance of the safety and effectiveness of the de-
12 vices. The Secretary shall publish in the Federal
13 Register a list of the devices or types of devices so
14 identified, and shall revise the list as appropriate.
15 The exemption for each device or type included on
16 the list is terminated upon the publication of the
17 list. For each report under subsection (k) submitted
18 pursuant to this subparagraph the Secretary shall
19 require the validation data described in paragraph
20 (1)(A).

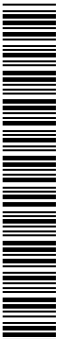
21 “(B) For each device or type of device included
22 on the list under subparagraph (A), a report under
23 subsection (k) shall be submitted to the Secretary
24 not later than 15 months after the publication of the
25 initial list, or a revision of the list, whichever termi-



1 nates the exemption for the device. During such 15-
2 month period, the Secretary may not take any action
3 under this Act against such device solely on the
4 basis that such report has not been submitted to the
5 Secretary. After the submission of the report to the
6 Secretary the Secretary may not determine that the
7 device is misbranded under section 502(o), adulter-
8 ated under section 501(f)(1)(B), or take action
9 against the device under section 301(p) for failure to
10 provide any information required by subsection (k)
11 until (i) the review is terminated by withdrawal of
12 the submission; (ii) the Secretary determines by
13 order that the device is substantially equivalent to a
14 predicate device; or (iii) the Secretary determines by
15 order that the device is not substantially equivalent
16 to a predicate device. Upon a determination that a
17 device is not substantially equivalent to a predicate
18 device, the device can no longer be legally marketed.

19 “(C) The initial list under subparagraph (A)
20 shall be published not later than 18 months after
21 the effective date of this subsection.

22 “(D) Section 502(o) applies with respect to the
23 failure to submit a report under subsection (k) that
24 is required pursuant to subparagraph (A), including



1 a failure of the report to include validation data re-
2 quired in such subparagraph.

3 “(E) The termination under subparagraph (A) of an
4 exemption under subsection (l) or (m) for a critical or
5 semicritical reprocessed single-use device does not termi-
6 nate the exemption under subsection (l) or (m) for the
7 original device.

8 “(3) In the case of a reprocessed single-use device
9 that is classified in class III and for which a premarket
10 application is required, the following provisions apply with
11 respect to such reprocessed device in lieu of an application
12 for premarket approval under section 515:

13 “(A) The device shall not be introduced into
14 interstate commerce or delivered for introduction
15 into interstate commerce unless the person involved
16 has submitted to the Secretary a report in accord-
17 ance with this paragraph and the Secretary, after
18 reviewing the report, issues an order determining
19 there is a reasonable assurance of the safety and ef-
20 fectiveness for the device.

21 “(B) The report under subparagraph (A) shall
22 contain the following:

23 “(i) The device name, including both the
24 trade or proprietary name and the common or
25 usual name.



1 “(ii) The establishment registration num-
2 ber of the owner or operator submitting the re-
3 port.

4 “(iii) Actions taken to comply with per-
5 formance standards under section 514.

6 “(iv) Proposed labels, labeling, and adver-
7 tising sufficient to describe the device, its in-
8 tended use, and directions for use.

9 “(v) Full reports of all information, pub-
10 lished or known to or which should be reason-
11 ably known to the applicant, concerning inves-
12 tigations which have been made to show wheth-
13 er or not a device is safe or effective.

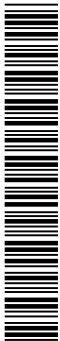
14 “(vi) A description of the device’s compo-
15 nents, ingredients, and properties.

16 “(vii) A full description of the methods
17 used in, and the facilities and controls used for,
18 the reprocessing and packing of the device.

19 “(viii) Such samples of the device that the
20 Secretary may reasonably require.

21 “(ix) A financial certification or disclosure
22 statement or both, as required by part 54 of
23 title 21, Code of Federal Regulations.

24 “(x) A statement that the applicant be-
25 lieves to the best of the applicant’s knowledge



1 that all data and information submitted to the
2 Secretary are truthful and accurate and that no
3 material fact has been omitted in the report.

4 “(xi) Any additional data and information
5 that the Secretary determines is necessary to
6 determine whether there is reasonable assur-
7 ance of safety and effectiveness for the repro-
8 cessed device.

9 “(C) In addition to the information or data re-
10 quired in subparagraph (B), the report under sub-
11 paragraph (A) shall include the validation data de-
12 scribed in paragraph (1)(A) that demonstrates that
13 the reasonable assurance of the safety or effective-
14 ness of the device will remain after the maximum
15 number of times the device is reprocessed as in-
16 tended by the person submitting the report under
17 this paragraph.”.

18 (c) DEFINITIONS.—Section 201 of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by
20 adding at the end the following:

21 “(11)(1) The term ‘single-use device’ means a device
22 that is intended for one use, or on a single patient during
23 a single procedure.

24 “(2)(A) The term ‘reprocessed’, with respect to a sin-
25 gle-use device, means an original device that has pre-



1 viously been used on a patient and has been subjected to
2 additional processing and manufacturing for the purpose
3 of an additional single use on a patient. The subsequent
4 processing and manufacture of a reprocessed single-use
5 device shall result in a device that is reprocessed within
6 the meaning of this definition.

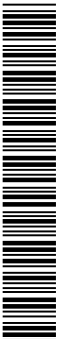
7 “(B) A single-use device that meets the definition
8 under subparagraph (A) shall be considered a reprocessed
9 device without regard to any description of the device used
10 by the manufacturer of the device or other persons, includ-
11 ing a description that uses the term ‘recycled’ rather than
12 the term ‘reprocessed’.

13 “(3) The term ‘original device’ means a new, unused
14 single-use device.

15 “(mm)(1) The term ‘critical reprocessed single-use
16 device’ means a reprocessed single-use device that is in-
17 tended to contact normally sterile tissue or body spaces
18 during use.

19 “(2) The term ‘semi-critical reprocessed single-use
20 device’ means a reprocessed single-use device that is in-
21 tended to contact intact mucous membranes and not pene-
22 trate normally sterile areas of the body.”.

23 (d) PROHIBITED ACTS.—Section 301 of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as



1 amended by section 321(b)(2) of Public Law 107–188, is
2 amended by adding at the end the following:
3 “(gg) The introduction or delivery for introduction
4 into interstate commerce of any device in violation of sec-
5 tion 510(o)(3).”.

